Test Procedure for §170.304 (c) Record Demographics

This document describes the draft test procedure for evaluating conformance of complete EHRs or EHR modules[1] to the certification criteria defined in 45 CFR Part 170 Subpart C of the Final Rule for Health Information Technology: Initial Set of standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology as published in the Federal Register on July 28, 2010. The document[2] is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at http://healthcare.nist.gov/docs/TestProcedureOverview_v1.pdf. The test procedures may be updated to reflect on-going feedback received during the certification activities.

The HHS/Office of the National Coordinator for Health Information Technology (ONC) has defined the standards, implementation guides and certification criteria used in this test procedure. Applicability and interpretation of the standards, implementation guides and certification criteria to EHR technology is determined by ONC. Test procedures to evaluate conformance of EHR technology to ONC's requirements are defined by NIST. Testing of EHR technology is carried out by ONC-Authorized Testing and Certification Bodies (ATCBs), not NIST, as set forth in the final rule establishing the Temporary Certification Program (*Establishment of the Temporary Certification Program for Health Information Technology, 45 CFR Part 170; June 24, 2010.*)

Questions about the applicability of the standards, implementation guides or criteria should be directed to ONC at ONC.Certification@hhs.gov. Questions about the test procedures should be directed to NIST at hit-tst-fdbk@nist.gov. Note that NIST will automatically forward to ONC any questions regarding the applicability of the standards, implementation guides or criteria. Questions about functions and activities of the ATCBs should be directed to ONC at ONC.Certification@hhs.gov .

CERTIFICATION CRITERIA

This Certification Criterion is from the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Final Rule issued by the Department of Health and Human Services (HHS) on July 28, 2010.

§170.304 (c) Record demographics. Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, and date of birth. Enable race and ethnicity to be recorded in accordance with the standard specified at §170.207(f).

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[1] Department of Health and Human Services, 45 CFR Part 170 Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule, July 28, 2010.

[2] Disclaimer: Certain commercial products are identified in this document. Such identification does not imply recommendation or endorsement by the National Institute of Standards and Technology.

Per Section III.D of the preamble of the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule where the record demographics certification criterion is discussed:

- "In the Medicare and Medicaid EHR Incentive Programs proposed rule (75 FR 1855), CMS stated that race and ethnicity codes should follow current Federal standards. We note that the OMB race and ethnicity codes constitute a government-unique standard for the purposes of the National Technology Transfer and Advancement Act of 1995 (NTTAA). We have adopted this standard because it provides an easily understood structure and format for electronically transmitting the data elements identified in the meaningful use Stage 1 objective, the standard is readily available, in general it provides the best standard to use to support our policies goals."

- "…we do not believe that it would be appropriate to expand this certification criterion beyond what is required to support meaningful use. Again, as we have previously stated, this does not preclude a Complete EHR or EHR Module developer from including the capability to record additional demographic information. Finally, consistent with the Medicare and Medicaid EHR Incentive Programs final rule, we have removed the capability to record insurance type from the certification criterion."

INFORMATIVE TEST DESCRIPTION

This section provides an informative description of how the test procedure is organized and conducted. It is not intended to provide normative statements of the certification requirements.

This test evaluates the capability for a Complete EHR or EHR Module to enable a user to electronically record, modify, and retrieve a patient's demographic data describing their preferred language, gender, race, ethnicity, and date of birth. Per the FR criteria, the test procedure does not evaluate the ability to record, modify and retrieve other types of patient demographic information.

This test procedure is organized into three sections:

- Record - evaluates the capability to enter patient demographic data into the EHR
  - o The Tester enters the NIST-supplied patient preferred language, gender, race, ethnicity, and date of birth

- Modify – evaluates the capability to modify patient demographic data that were entered into the EHR during the Record test
  - o The Tester displays the patient preferred language, gender, race, ethnicity, and date of birth data entered during the Record Patient Demographics test
  - o The Tester modifies these demographic data using NIST-supplied patient preferred language, gender, race, ethnicity, and date of birth data
  - o Please note – The retention of previous version(s) of demo data entered into the EHR is not addressed by the criteria and thus outside the scope of this test procedure

- Retrieve – evaluates the capability to display the patient demographic data that were entered into the EHR during the Record test and Modify test
  - The Tester displays the patient preferred language, gender, race, ethnicity, and date of birth data entered during the Record Patient Demographics and Modify Patient Demographics tests
  - The Tester validates that the displayed demographic data are accurate and complete

REFERENCED STANDARDS

§170.207 Vocabulary standards for representing electronic health information.	Regulatory Referenced Standard
(f) Race and Ethnicity. Standard. The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity,Statistical Policy Directive No. 15, October 30, 1997 (available at http://www.whitehouse.gov/omb/rewrite/fedreg/ombdir15.html).	

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.304.c – 1: Electronically Record Patient Demographics

DTR170.304.c – 2: Electronically Modify Patient Demographics

DTR170.304.c – 3: Electronically Retrieve Patient Demographics

DTR170.304.c – 1: Electronically Record Patient Demographics

Required Vendor Information

VE170.304.c – 1.01:   Vendor shall identify the EHR function(s) that are available to: 1) enter a patient's preferred language, gender, race, ethnicity, and date of birth, 2) modify these demographic data, and 3) retrieve these demographic data

Required Test Procedure:

TE170.304.c – 1.01:   Tester shall select patient demographic data from NIST-supplied test data sets in TD170.304.c – 1

TE170.304.c – 1.02:   Using the EHR function(s) identified by the Vendor, the Tester shall enter demographic data from the test data sets in TD170.304.c – 1, including

- the patient's preferred language
- the patient's gender
- the patient's race
- the patient's ethnicity
- the patient's date of birth

TE170.304.c – 1.03:   Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the patient demographic test data are entered correctly and without omission

Inspection Test Guide

IN170.304.c – 1.01:   Using the data in the NIST-supplied Test Data set TD170.304.c – 1, Tester shall verify that the patient demographic test data were entered correctly and without omission

IN170.304.c – 1.02:   Tester shall verify that the patient demographic data entered during the test are stored in the patient's record, including

- the patient's preferred language
- the patient's gender
- the patient's race
- the patient's ethnicity
- the patient's date of birth

DTR170.304.c – 2: Electronically Modify Patient Demographics

Required Vendor Information

- As defined in DTR170.304.c – 1, no additional information is required

Required Test Procedure:

TE170.304.c – 2.01:   Tester shall select patient demographic test data from NIST-supplied test data sets in TD170.304.c – 2

TE170.304.c – 2.02:   Using the EHR function(s) identified by the Vendor, the Tester shall select the existing patient record, shall display the patient demographic data entered during the DTR170.304.c – 1: Electronically Record Patient Demographics test, and shall modify these demographic data, including

- the patient's preferred language
- the patient's gender
- the patient's race
- the patient's ethnicity
- the patient's date of birth

TE170.304.c – 2.03:   Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the patient demographic data modified in TE170.304.c – 2.02 are modified correctly and without omission

Inspection Test Guide:

IN170.304.c – 2.01:   Using the data in the NIST-supplied Test Data set TD170.304.c – 2, Tester shall verify that the patient demographic data entered during the DTR170.304.c – 1: Electronically Record Patient Demographics test were accessed and modified correctly and without omission

IN170.304.c – 2.02:   Tester shall verify that the modified demographic data are stored in the patient's record, including the revised version of

- the patient's preferred language

- the patient's gender
- the patient's race
- the patient's ethnicity
- the patient's date of birth

DTR170.304.c – 3: Electronically Retrieve Patient Demographics

Required Vendor Information
- As defined in DTR170.304.c – 1, no additional information is required

Required Test Procedure:

TE170.304.c – 3.01:   Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and shall display the patient demographic data the Tester entered during the DTR170.304.c – 2: Electronically Modify Patient Demographics tests, including
- the patient's preferred language
- the patient's gender
- the patient's race
- the patient's ethnicity
- the patient's date of birth

TE170.304.c – 3.02:   Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the patient demographic test data display correctly and without omission

Inspection Test Guide

IN170.304.c – 3.01:   Using the data in the NIST-supplied Test Data set TD170.304.c – 2, Tester shall verify that the patient demographic data entered in the DTR170.304.c – 1: Electronically Record Patient Demographics test and modified in the DTR170.304.c – 2: Electronically Modify Patient Demographics test display correctly and without omission, including
- the patient's preferred language
- the patient's gender
- the patient's race
- the patient's ethnicity
- the patient's date of birth

TEST DATA

Test data is provided by NIST in this Test Procedure to ensure that the functional and interoperable requirements identified in the criteria can be adequately evaluated for conformance, as well as to provide consistency in the testing process across multiple ONC-Authorized Testing and Certification Bodies (ATCBs). The NIST-supplied test data focus on evaluating the basic capabilities required of EHR technology, rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support. The test data is formatted for readability of use within the testing process. The

format is not prescribing a particular end-user view or rendering. No additional requirements should be drawn from the format.

The Tester shall use and apply the NIST-supplied test data during the test, without exception, unless one of the following conditions exist:

- The Tester determines that the Vendor product is sufficiently specialized that the NIST-supplied test data needs to be modified in order to conduct an adequate test. Having made the determination that some modification to the NIST-supplied test data is necessary, the Tester shall record the modifications made as part of the test documentation.
- The Tester determines that changes to the test data will improve the efficiency of the testing process; primarily through using consistent demographic data throughout the testing workflow. The tester shall ensure that the functional and interoperable requirements identified in the criterion can be adequately evaluated for conformance and that the test data provides a comparable level of robustness.

Any departure from the NIST-supplied test data shall strictly focus on meeting the basic capabilities required of EHR technology relative to the certification criterion rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support.

The Test Procedures require that the Tester enter the test data into the EHR technology being evaluated for conformance. The intent is that the Tester fully control the process of entering the test data in order to ensure that the data are correctly entered as specified in the test procedure. If a situation arises where it is impractical for a Tester to directly enter the test data, the Tester, at the tester's discretion, may instruct the Vendor to enter the test data, so long as the Tester remains in full control of the testing process, directly observes the test data being entered by the Vendor, and validates that the test data are entered correctly as specified in the test procedure.

TD170.304.c – 1: Record Patient Demographics

<u>Demographics Test Data – Set 1</u> (Race and Ethnicity terms are from the OMB Standards for Maintaining, Collecting, and Presenting Federal Data)

Preferred Language:	English
Gender:	Female
Race:	White
Ethnicity:	Not Hispanic or Latino
Date of Birth:	05/26/1952

<u>Demographics Test Data – Set 2</u> (Race and Ethnicity terms are from the OMB Standards for Maintaining, Collecting, and Presenting Federal Data)

Preferred Language:	Japanese
Gender:	Female
Race:	Asian
Ethnicity:	Not Hispanic or Latino
Date of Birth:	04/30/1945

Demographics Test Data – Set 3 (Race and Ethnicity terms are from the OMB Standards for Maintaining, Collecting, and Presenting Federal Data)

Preferred Language: French
Gender: Male
Race: Asian
Ethnicity: Not Hispanic or Latino
Date of Birth: 02/27/1980

Demographics Test Data – Set 4 (Race and Ethnicity terms are from the OMB Standards for Maintaining, Collecting, and Presenting Federal Data)

Preferred Language: Italian
Gender: Male
Race: White
Ethnicity: Hispanic or Latino
Date of Birth: 09/17/1975

Demographics Test Data – Set 5 (Race and Ethnicity terms are from the OMB Standards for Maintaining, Collecting, and Presenting Federal Data)

Preferred Language: Portuguese
Gender: Female
Race: White
Ethnicity: Hispanic or Latino
Date of Birth: 08/07/1955

TD170.304.c – 2: Modify Patient Demographics

Demographics Test Data – Set 1 (Race and Ethnicity terms are from the OMB Standards for Maintaining, Collecting, and Presenting Federal Data)

Change Preferred Language from English to **Spanish**
Change Gender from Female to **Male**
Change Race from White to **Black or African American**
Change Ethnicity from Not Hispanic or Latino to **Hispanic or Latino**
Change Date of Birth from 05/26/1952 to **07/27/1925**

Revised Demographics Data

Preferred Language: Spanish
Gender: Male
Race: Black or African American
Ethnicity: Hispanic or Latino
Date of Birth: 07/27/1925

Demographics Test Data – Set 2 (Race and Ethnicity terms are from the OMB Standards for Maintaining, Collecting, and Presenting Federal Data)

Change Preferred Language from Japanese to **English**
Change Gender from Female to **Male**

Change Race from Asian to **White**
Change Ethnicity from Not Hispanic or Latino to **Hispanic or Latino**
Change Date of Birth from 04/30/1945 to **04/03/1945**

Revised Demographics Data

Preferred Language:	English
Gender:	Male
Race:	White
Ethnicity:	Hispanic or Latino
Date of Birth:	04/03/1945

Demographics Test Data – Set 3 (Race and Ethnicity terms are from the OMB Standards for Maintaining, Collecting, and Presenting Federal Data)

Change Preferred Language from French to **Spanish**
Change Gender from Male to **Female**
Change Race from Asian to **Black or African American**
Change Ethnicity from Not Hispanic or Latino to **Hispanic or Latino**
Change Date of Birth from 02/27/1980 to **03/27/1980**

Revised Demographics Data

Preferred Language:	Spanish
Gender:	Female
Race:	Black or African American
Ethnicity:	Hispanic or Latino
Date of Birth:	03/27/1980

Demographics Test Data – Set 4 (Race and Ethnicity terms are from the OMB Standards for Maintaining, Collecting, and Presenting Federal Data)

Change Preferred Language from Italian to **Spanish**
Change Gender from Male to **Female**
Change Race from White to **Native Hawaiian or Other Pacific Islander**
Change Ethnicity from Hispanic or Latino to **Not Hispanic or Latino**
Change Date of Birth from 09/17/1975 to **09/27/1965**

Revised Demographics Data

Preferred Language:	Spanish
Gender:	Female
Race:	Native Hawaiian or other Pacific islander
Ethnicity:	Not Hispanic or Latino
Date of Birth:	09/27/1965

Demographics Test Data – Set 5 (Race and Ethnicity terms are from the OMB Standards for Maintaining, Collecting, and Presenting Federal Data)

Change Preferred Language from Portuguese to **Russian**
Change Race from White to **Native Hawaiian or Other Pacific Islander**
Change Ethnicity from Hispanic or Latino to **Not Hispanic or Latino**

Change Date of Birth from 08/07/1955 to **07/07/1955**

<u>Revised Demographics Data</u>

Preferred Language: Russian
Gender: Female
Race: Native Hawaiian or Other Pacific Islander
Ethnicity: Not Hispanic or Latino
Date of Birth: 07/07/1955

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description	Date Published
0.7	Original draft version	March 19, 2010
1.0	Updated to reflect Final Rule	July 21, 2010
1.0	Updated to remove "Pending" from header	August 13, 2010